

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Paper .....	1,500	1	0.25	375.00
In-person .....	500	1	1.00	500.00
Total .....	28,000			5,883.00

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION:** To request more information on the proposed project, contact Paul L. Johnson, NIH NICHD Office of Science Policy, Analysis and Communication (OSPAC), 9000 Rockville Pike, Bldg. 31, Rm. 2A-18, Bethesda, Maryland 20892-2425, or call non-toll-free at 301-402-3213. You may also e-mail your request to [pjohnson@mail.nih.gov](mailto:pjohnson@mail.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: October 17, 2007.

**Paul L. Johnson,**

*Project Clearance Liaison, NICHD National Institutes of Health.*

[FR Doc. E7-20910 Filed 10-23-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### **Novel Micro-RNA Sequence Transforms Non-Functional T-Lymphocytes to Highly Functional: Key to Improved Immunotherapy for the Treatment of Cancers**

*Description of Technology:* This technology is directed to the therapeutic use of microRNA-181a in the adoptive immunotherapy of cancer.

The adoptive transfer of anti-tumor T cells after a lymphodepleting regimen can result in the regression of metastatic cancer both in mouse and human, but the production of highly-reactive, tumor-specific T cells still represents a barrier to broad implementation of T cell-based immunotherapies. This technology enables the use of microRNA (miR)-181a, a recently identified intrinsic modulator of T-cell receptor (TCR) signaling, to improve anti-tumor T cell responsiveness. Micro-RNAs are short RNA molecules that regulate the activity of genes and appear to control biological processes.

We found that genetic engineering of T lymphocytes with miR-181a dramatically augmented the function of poorly responsive human tumor-infiltrating lymphocytes and TCR-engineered peripheral blood lymphocytes, resulting in potent anti-tumor reactivity. Furthermore, in a

mouse model, miR-181a increased the function of self/tumor-specific CD8<sup>+</sup> T cells enabling effective tumor destruction in the absence of vaccination or exogenous cytokines that were otherwise essential requirements. This technology is the first reported use of a miRNA gene as tool in the treatment of disease.

*Applications:* The microRNA sequence ("miR-181a") can be used to enhance the tumor recognizing capacity of T-lymphocytes against several tumors.

This technology can be used for selective treatment of several cancers more effectively.

*Advantages:* Proof-of concept pre-clinical data are available and clinical trials are currently being planned.

This technology is based on adoptive immunotherapy, which is now an accepted and effective form of cancer treatment.

*Benefits:* The microRNA identified has the potential to broaden and enhance the scope of adoptive immunotherapy.

*Development Status:* Pre-clinical work has been completed and clinical studies are forthcoming.

*Inventors:* Dr. Nicholas P. Restifo et al. (NCI).

*Relevant Publication:* Q Li et al. miR-181a is an intrinsic modulator of T cell sensitivity and selection. *Cell*. 2007 Apr 6;129(1):147-161.

*Patent Status:* U.S. Provisional Application filed 25 May 2007 (HHS Reference No. E-224-2007/0-US-01).

*Licensing Status:* This technology is available for licensing under an exclusive or non-exclusive patent license.

*Licensing Contact:* Michelle A. Booden, PhD; 301/451-7337; [boodenm@mail.nih.gov](mailto:boodenm@mail.nih.gov).

*Collaborative Research Opportunity:* The Surgery Branch of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the therapeutic use of microRNA-181a in the adoptive immunotherapy of cancer. Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

### Use of HDAC Inhibitors for the Prevention and Cure for Brain Metastases of Cancers

*Description of Technology:* The increased survival of primary and metastatic cancers consequential of improved therapies has resulted in increased brain metastases. Few treatment options are available for cancer patients with central nervous system (CNS) metastasis. There is a need for new treatment options for CNS metastases especially brain metastases originating outside the CNS.

The present invention provides a method of treating a localized carcinoma CNS metastasis of extra-CNS origin. More specifically, the method comprises of treating a localized carcinoma CNS metastasis of extra-CNS origin with a histone deacetylase (HDAC) inhibitor (HDACI) originating in one or more organs such as lung, breast, liver, colon, and prostate. The HDACI can be any HDACI that is capable of crossing the blood-brain barrier (BBB) such as vorinostat.

*Advantages:* Vorinostat has been approved by the FDA for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies, and as such, has efficacy and tolerability data.

*Benefits:* More than 40,000 breast cancer deaths are estimated to occur in 2007. Majority of these deaths are due to metastases of the breast cancer. Approximately, 10%–20% of women with metastatic breast cancer are estimated to develop brain metastasis and the median survival after brain cancer metastasis is only one year. This technology may effectively treat breast cancer brain metastases and thus improve overall survival and quality of life of patients suffering from cancer. The current cancer chemotherapeutic market is valued at \$42 billion and expected to grow.

*Inventors:* Patricia S. Steeg et al. (NCI).

*Development Status:* *In vivo* animal model data available with vorinostat.

*Patent Status:* U.S. Provisional Application No. 60/891,856 filed 02 Feb 2007 (HHS Reference No. E-084-2007/0-US-01).

*Licensing Contact:* John Stansberry; 301/435-5236; [stansbej@mail.nih.gov](mailto:stansbej@mail.nih.gov).

Dated: October 11, 2007.

#### Steven M. Ferguson,

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. E7-20909 Filed 10-23-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92-463, notice is hereby given of the fourteenth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 5:30 p.m. on Monday, November 19, 2007 and 8:30 a.m. to approximately 5:30 p.m. on Tuesday, November 20, 2007, at the Ronald Reagan Building and International Trade Center—1300 Pennsylvania Avenue, NW., Washington, DC 20004. The meeting will be open to the public with attendance limited to space available. The meeting also will be Web cast.

The agenda will focus on three key issues—finalization of the SACGHS report on the opportunities and challenges in realizing the promise of pharmacogenomics; the oversight of genetic testing; and the preparedness of health professionals to incorporate genetic and genomic tests and services into clinical and public health practice. With regard to the oversight of genetic testing, SACGHS' draft report to the Secretary of Health and Human Services will be released for public comment in early November. The Committee will provide an extended period of time during the November meeting for members of the public to provide their perspectives on the oversight issues and comments on the Committee's draft report and recommendations. The Committee will also be briefed about an international analysis of oversight systems for genetic testing with a focus on the U.S. system.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [carr@od.nih.gov](mailto:carr@od.nih.gov). The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who is in need of special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service

Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: <http://www4.od.nih.gov/oba/sacghs.htm>.

Dated: October 17, 2007.

#### Jennifer Spaeth,

*Director, NIH Office of Federal Advisory Committee Policy.*

[FR Doc. 07-5240 Filed 10-23-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Small Grants for Behavioral Research in Cancer Control [R03].

*Date:* November 14, 2007.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Rhonda J. Moore, PhD., Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Suite 701, Room 7151, Bethesda, MD 20892-8329, 301-451-9385, [moorerh@mail.nih.gov](mailto:moorerh@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Community Clinical Oncology Program & Minority Based Community Clinical Oncology.